Risk-Based CMC Review

GMP Breakout Sessions

Summary

JUNE 12

Use Current Inspection System

- Site specific
- Profile class (dosage form type) specific
- Includes assessment of current GMP status
- Includes product specific coverage as deemed necessary by CDER or Field Office
- System works

Use Current System Plus

- Additional assessment of long-term compliance with GMP's and control capabilities
  - information from annual product reviews
  - GMP-related recall history
  - management responsiveness to correcting GMP deficiencies
  - history of PAI inspections
  - body of evidence relating to effectiveness of controls
  - status of previous regulatory actions
    - corrections in place
    - repetitive nature of system deficiencies

Other Issues

- AIP and consent decree firms should serve a probationary period
- Consider implications of MRA
- Current System Plus may create different GMP standards for low and high risk drugs
- Differential impact on new/old, small/large companies

Other Issues (continued)

- Multiple companies in production/supply chain
- Change in ownership, management, or relevant personnel
- TANDA's -- would not meet "Current System Plus"